

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

The Effect of Telenursing on Maternal-Infant Attachment and Stress among Premature Infant's Mothers who Hospitalized in Neonatal Intensive Care Unit of the Shahid Beheshti Hospital 2017.

Protocol summary

Summary

Objective: This study aimed to determine the efficacy of Telenursing on maternal-infant attachment and stress on preterm infant's mothers in NICU. **Design:** This study is a clinical trial that will be conducted in Isfahan. **Setting and conduct:** In this study, 50 mothers of preterm infants with inclusion criteria admitted in NICU of the Isfahan Shahid Beheshti hospital randomly assigned to an experimental group and a control group. **Participants** including major eligibility criteria: Gestational Age 33-37 week with no evidence of physical or congenital problem and no Deterioration of their disease. **Intervention:** In the experimental group within seven days after birth until a week after discharge nursing education with Telenursing will be done by telephone system. This telephone system consist of two parts offline and online. Off line system have 10 codes with recorded information about NICU, characterization of premature newborns, changes of weight, length and head circumstances in premature newborns, therapeutic procedures in premature newborns, equipment in NICU, relaxing premature newborns, different methods of feeding in premature newborns, breast milk storage and handling, ways of increasing milk expression, listening to relaxation voice messages. The offline system will be always available by phone during 24 hours. In online part mothers can contact to the researcher and ask their questions. **Control groups** received only routine interventions. **variables:** During seven days after birth both groups will complete Parental Stress Scale: Neonatal Intensive Care Unit (PSS:NICU) and Maternal Postnatal Attachment (MPA) scale, on the day of discharge they will complete PSS:NICU and a week after discharge, they will complete MPA scale.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017052034040N1**

Registration date: **2017-11-06, 1396/08/15**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-11-06, 1396/08/15

Registrant information

Name

Zahra Alsadat Jafarzadeh

Name of organization / entity

Isfahan University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2017-06-10, 1396/03/20

Expected recruitment end date

2017-11-11, 1396/08/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Telenursing on Maternal-Infant Attachment and Stress among Premature Infant's Mothers who Hospitalized in Neonatal Intensive Care Unit of the Shahid Beheshti Hospital 2017.

Public title

The Effect of Telenursing on Maternal-Infant Attachment and Stress on Premature Infant's Mothers.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Mother's consent to participate the study; Mothers who able to read and write; Parents who are non-employed in medical and paramedical jobs; No evidence of maternal physical or psychological condition that effect maternal supportive care role like postpartum depression, anxiety, addiction; No evidence of major stress like divorce, impersonate of husband or death of family member during last year; Gestational Age 33-37 weeks; Newborns who have taken Kangaroo Mother Care(KMC); No evidence of neonatal extreme condition like grades third or fourth Internal Ventricular Hemorrhage (IVH) or physical or congenital problem; Mothers who are not participating in any other research. Exclusion criteria: Intention of mothers to leave the study; Evidence of any maternal physical or psychological problem during the study that prevent her to do supportive care role for her neonate; Less than two contacts from the mothers; Discharge of newborns before the end of the study; Deterioration of the disease, or death of the neonates;

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 50

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

Ethics committee of Isfahan University of Medical Science, Nursing Midwifery School, Isfahan University of Medical Science, Hezarjereeb Street, Isfahan, Iran

City

Isfahan

Postal code

۸۱۷۴۶-۷۳۴۶۱

Approval date

2017-02-19, 1395/12/01

Ethics committee reference number

IR.MUI.REC.1390.3.899

Health conditions studied

1

Description of health condition studied

stress

ICD-10 code

R45.7

ICD-10 code description

State of emotional shock and stress

2

Description of health condition studied

attachment

ICD-10 code

F93

ICD-10 code description

Emotional disorders with onset specific to childhood

Primary outcomes

1

Description

stress

Timepoint

During seven days after birth, The day of discharge.

Method of measurement

Stress with Parental Stress Scale: Neonatal Intensive Care Unit (PSS:NICU)

2

Description

attachment

Timepoint

During seven days after birth, One week after discharge

Method of measurement

Maternal Postnatal Attachment (MPA).

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group receive Telenursing. Telenursing consist of two parts (offline and online). Off line system have 10 codes with recorded information about NICU, characterization of premature newborns, changes of weight, length and head circumstances in premature newborns, therapeutic procedures in premature newborns, equipment in NICU, relaxing premature newborns, different methods of feeding in premature newborns, breast milk storage and handling, ways of increasing milk expression, listening to relaxation voice messages) and the offline system will be always available by phone during 24 hours. In online part mothers can contact to the researcher and ask their questions. Telenursing starts with in a week after newborn hospitalization until a week after discharge.

Category

N/A

2

Description

Control groups received only routine interventions. Before discharge all samples receive pamphlet about Kangaroo Mother Care (KMC).

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti hospital

Full name of responsible person

Zahra Alsadat Jafarzadeh

Street address

Shahid Beheshti, Ostad Motahari street, Isfahan, Iran.

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice for research, Isfahan University of Medical Sciences

Full name of responsible person

Sara Arti

Street address

nursing midwifery school, Isfahan University of

Medical Science, Hezarjereeb Street, Isfahan, Iran

City

Isfahan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice for research, Isfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Zahra Alsadat Jafarzadeh

Position

postgraduated nursing student

Other areas of specialty/work

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City

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty